



07-28-05

IFW

PATENT
Attorney Docket No. 223467

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Woo et al.

Group Art Unit: 1623

Application No. 10/802,282

Examiner: Unassigned

Filed: March 17, 2004

For: LYOPHILIZED AZITHROMYCIN
FORMULATION

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date

of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

or

☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

- ☐ Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.
- ☒ This patent application was filed after June 30, 2003. Accordingly, copies of U.S. patents and patent applications that are listed on the accompanying Form 1449 are not enclosed herewith (see Official Gazette Notice of August 5, 2003). Copies of other references identified on the accompanying Form 1449 are enclosed herewith.
- ☒ Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were

furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- ☒ **No fee** is owed by the applicant(s).
- ☐ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

In re Appln. of Woo et al.
Application No. 10/802,282

Method of Payment of Fees


- ☐ Attached is a check in the amount of \$.
☐ Charge Deposit Account No. 12-1216 in the amount of \$. (A duplicate copy of this communication is enclosed for that purpose.)

Authorization to Charge Additional Fees

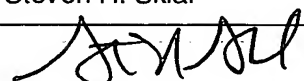
- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

Instructions as to Overpayment

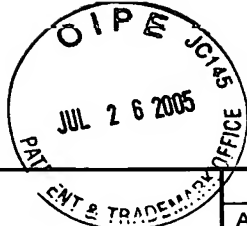
- ☒ Credit Account No. 12-1216.
☐ Refund


Steven H. Sklar, Reg. No. 42,154
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
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(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: July 26, 2005

MAILING/TRANSMISSION CERTIFICATE UNDER 37 CFR 1.8 OR 1.10			
I hereby certify that this document and all accompanying documents are, on the date indicated below, being <input checked="" type="checkbox"/> deposited with the U.S. Postal Service using "Express Mail" service in an envelope addressed in the same manner indicated on this document with Express Mail Label Number EV 420401644 US, <input type="checkbox"/> deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed in the same manner indicated on this document, or <input type="checkbox"/> facsimile transmitted to the U.S. Patent and Trademark Office at fax number: (571) 273-8300.			
Name (Print/Type)	Steven H. Sklar		
Signature		Date	July 26, 2005

Please type a plus sign (+) inside this box →



Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/802,282
Filing Date	March 17, 2004
First Named Inventor	Woo et al.
Group Art Unit	1623
Examiner Name	Unassigned
Attorney Docket Number	223467

Sheet 1 of 6

U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	A U	2,653,899		Bunch et al.	September 29, 1953	
	A V	3,417,077		Murphy et al.	December 17, 1968	
	AW	3,478,014		Djokic et al.	November 11, 1969	
	A X	4,020,270		Arcamone et al.	April 26, 1977	
	A Y	4,219,641		Desposato et al.	August 26, 1980	
	A Z	4,328,334		Kobrehel et al.	May 4, 1982	
	B A	4,465,674		Bright et al.	August 14, 1984	
	B B	4,474,768		Bright	October 2, 1984	
	B C	4,512,982		Hauske et al.	April 23, 1985	
	B D	4,517,359		Kobrehel et al.	May 14, 1985	
	B E	4,518,590		Hauske et al.	May 21, 1985	
	B F	4,526,889		Bright	July 2, 1985	
	B G	4,963,531		Remington	October 16, 1990	
	B H	5,023,085		Francoeur et al.	June 11, 1991	
	B I	5,250,518		Kobrehel et al.	October 5, 1993	
	B J	5,332,807		Waddell et al.	July 26, 1994	
	B K	5,441,939		Yang	August 15, 1995	
	B L	5,674,911		Emanuele et al.	October 7, 1997	
	B M	5,686,587		Yang	November 11, 1997	
	B N	5,747,058		Tipton et al.	May 5, 1998	
	B O	5,760,010		Klein	June 2, 1998	
	B P	5,786,338		Klein	July 28, 1998	
	B Q	5,795,871		Narita et al.	August 18, 1998	
	B R	5,811,088		Hunter et al.	September 22, 1998	
	B S	5,869,629		Bayod Jasanda et al.	February 9, 1999	
	B T	5,885,601		Sokal	March 23, 1999	
	B U	5,958,888		Macy et al.	September 28, 1999	
	B V	6,013,778		Heggie et al.	January 11, 2000	
	B W	6,025,350		Masamune et al.	February 15, 2000	
	B X	6,043,225		Shor et al.	March 28, 2000	
	B Y	6,054,133		Horwitz et al.	April 25, 2000	
	B Z	6,172,069	B1	Klimstra et al.	January 9, 2001	
	C A	6,174,865	B1	Klein	January 16, 2001	
	C B	6,218,368	B1	Wirostko	April 17, 2001	
	C C	6,239,112	B1	Macy et al.	May 29, 2001	
	C D	6,245,903	B1	Karimian et al.	June 12, 2001	
	C E	6,281,199	B1	Gupta	August 28, 2001	
	C F	6,339,063	B1	Kropp et al.	January 15, 2002	
	C G	6,369,035	B1	Kobrehel et al.	April 9, 2002	
	C H	6,383,471	B1	Chen et al.	May 7, 2002	

Examiner Signature

Date Considered

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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				Group Art Unit	1623
				Examiner Name	Unassigned
Sheet	2	of	6	Attorney Docket Number	223467

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	C I	6,407,074	B1	Bronk et al.	June 18, 2002	
	C J	6,420,536	B1	Bronk et al.	July 16, 2002	
	C K	6,420,537	B1	Bosch et al.	July 16, 2002	
	C L	6,451,990	B1	Bayod Jasanada et al.	September 17, 2002	
	C M	6,465,437	B1	Rafka et al.	October 15, 2002	
	C N	6,500,987	B1	Schwartz et al.	December 31, 2002	
	C O	6,504,017	B1	Bosch et al.	January 7, 2003	
	C P	6,528,492	B1	de la Torre Garcia et al.	March 4, 2003	
	C Q	6,586,576	B2	Aronhime et al.	July 1, 2003	
	C R	6,645,528	B1	Straub et al.	November 11, 2003	
	C S	6,703,372	B1	Centellas et al.	March 9, 2004	
	C T	6,720,001	B2	Chen et al.	April 13, 2004	
	C U	6,723,341	B2	Rudnic et al.	April 20, 2004	
	C V	6,761,895	B2	Sawada et al.	July 13, 2004	
	C W	6,764,997	B2	Tenengauzer et al.	July 20, 2004	
	C X	6,777,393	B2	Bronk et al.	August 17, 2004	
	C Y	6,825,327	B2	Sklavounos et al.	November 30, 2004	
	C Z	6,861,413	B2	Li et al.	March 1, 2005	
	D A	2001/0014670	A1	Balin et al.	August 16, 2001	
	D B	2001/0047089	A1	Aronhime et al.	November 29, 2001	
	D C	2001/0048944	A1	Rudnic et al.	December 6, 2001	
	D D	2002/0007049	A1	Singer et al.	January 17, 2002	
	D E	2002/0012680	A1	Patel et al.	January 31, 2002	
	D F	2002/0022054	A1	Sawada et al.	February 21, 2002	
	D G	2002/0028920	A1	Lifshitz et al.	March 7, 2002	
	D H	2002/0044965	A1	Curatolo et al.	April 18, 2002	
	D I	2002/0049167	A1	Abraham et al.	April 25, 2002	
	D J	2002/0061858	A1	Bronk et al.	May 23, 2002	
	D K	2002/0071822	A1	Uhrich	June 13, 2002	
	D L	2002/0086867	A1	Dubois et al.	July 4, 2002	
	D M	2002/0107265	A1	Chen et al.	August 8, 2002	
	D N	2002/0111318	A1	Rengaraju	August 15, 2002	
	D O	2002/0115621	A1	Su et al.	August 22, 2002	
	D P	2002/0142050	A1	Straub et al.	October 3, 2002	
	D Q	2002/0143211	A1	Dolitzky et al.	October 3, 2002	
	D R	2002/0156026	A1	Bronk et al.	October 24, 2002	
	D S	2003/0007958	A1	Chen	January 9, 2003	
	D T	2003/0018030	A1	Garti et al.	January 23, 2003	
	D U	2003/0050620	A1	Odidi et al.	March 13, 2003	
	D V	2003/0064939	A1	Sklavounos et al.	April 3, 2003	

Examiner Signature	Date Considered
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Please type a plus sign (+) inside this box →



Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/802,282
				Filing Date	March 17, 2004
				First Named Inventor	Woo et al.
				Group Art Unit	1623
				Examiner Name	Unassigned
Sheet	3	of	6	Attorney Docket Number	223467

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	DW	2003/0092642	A1	Rafka et al.	May 15, 2003	
	D X	2003/0104055	A1	Rudnic et al.	June 5, 2003	
	D Y	2003/0105066	A1	Soldato et al.	June 5, 2003	
	D Z	2003/0108597	A1	Chancellor et al.	June 12, 2003	
	E A	2003/0119760	A1	Hussain et al.	June 26, 2003	
	E B	2003/0119865	A1	Dubois et al.	June 26, 2003	
	E C	2003/0139583	A1	Singh et al.	July 24, 2003	
	E D	2003/0143259	A1	Roy et al.	July 31, 2003	
	E E	2003/0148964	A1	Dunne	August 7, 2003	
	E F	2003/0162730	A1	Li et al.	August 28, 2003	
	E G	2003/0165563	A1	Murphy et al.	September 4, 2003	
	E H	2003/0176369	A1	Tenengauzer et al.	September 18, 2003	
	E I	2003/0190365	A1	Fergione et al.	October 9, 2003	
	E J	2003/0206951	A1	Rudnic et al.	November 6, 200	
	E K	2003/0207819	A1	Moskowitz	November 6, 2003	
	E L	2003/0215496	A1	Patel et al.	November 20, 2003	
	E M	2003/0228357	A1	Johnson et al.	December 11, 2003	
	E N	2003/0228381	A1	Qazi et al.	December 11, 2003	
	E O	2004/0009930	A1	Su et al.	January 15, 2004	
	E P	2004/0014951	A1	Dumic et al.	January 22, 2004	
	E Q	2004/0014952	A1	Rengaraju	January 22, 2004	
	E R	2004/0023896	A1	Bronk et al.	February 5, 2004	
	E S	2004/0023898	A1	Dunne	February 5, 2004	
	E T	2004/0033969	A1	Burnet et al.	February 19, 2004	
	E U	2004/0043944	A1	Li et al.	March 4, 2004	
	E V	2004/0043945	A1	Li et al.	March 4, 2004	
	EW	2004/0053862	A1	Centellas et al.	March 18, 2004	
	E X	2004/0082527	A1	Li et al.	April 29, 2004	
	E Y	2004/0087517	A1	Burnet et al.	May 6, 2004	
	E Z	2004/0087564	A1	Wright et al.	May 6, 2004	
	F A	2004/0091527	A1	Curatolo et al.	May 13, 2004	
	F B	2004/0092460	A1	Dumic et al.	May 13, 2004	
	F C	2004/0101557	A1	Gibson et al.	May 27, 2004	
	F D	2004/0109894	A1	Shefer et al.	June 10, 2004	
	F E	2004/0121966	A1	Li et al.	June 24, 2004	
	F F	2004/0132673	A1	Suh et al.	July 8, 2004	
	F G	2004/0138149	A1	Li et al.	July 15, 2004	
	F H	2004/0138150	A1	Santi et al.	July 15, 2004	
	F I	2004/0170617	A1	Finegold	September 2, 2004	

Examiner Signature	Date Considered
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Sheet	4	of	6
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[illegible]

Date Considered

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Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
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				Filing Date	March 17, 2004
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				Group Art Unit	1623
Examiner Name	Unassigned				
Sheet	5	of	6	Attorney Docket Number	223467

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	G B	CA	1,314,876		Pfizer Inc.	03/23/1993		
	G C	CN	1093370	A	Jicai Medicine Research Inst B	10/12/1994		+
	G D	CN	1114960	A	Jicai Medicine Inst Beijing	01/17/1996		+
	G E	CN	1123279	A	Shen Jiaxiang	05/29/1996		+
	G F	CN	1161971	A	Shijiazhuang Pharmaceutical GR	10/15/1997		+
	G G	CN	1205338	A	Liu Wanzhong	01/20/1999		+
	G H	EP	0101186	A1	Pfizer Inc.	02/22/1984		
	G I	EP	0284203	A2	Beecham Group PLC	09/28/1988		
	G J	EP	0298650	B1	Pfizer Inc.	01/11/1989		
	G K	EP	0307128	B1	Pfizer Inc.	03/15/1989		
	G L	EP	0445743	B1	Pliva Farmaceutska et al.	09/11/1991		
	G M	EP	0467331	A1	Pliva Farmaceutska et al.	01/22/1992		
	G N	EP	0677530	B1	Pliva, farmeceutska et al.	10/18/1995		
	G O	EP	0827965	A2	Astur-Pharma, S.A.	06/03/1998		
	G P	EP	0879823	B1	Hovione Inter Ltd.	11/25/1998		
	G Q	EP	0941999	A2	Hovione Inter Ltd.	09/15/1999		
	G R	EP	0984020	B1	Apotex, Inc.	07/24/2002		
	G S	EP	1103558	B1	Astur-Pharma, S.A.	06/25/2003		
	G T	EP	1227102	B1	Alembic Limited	03/31/2004		
	G U	EP	1234833	A2	Astur-Pharma, S.A.	03/12/2003		
	G V	EP	1400528	A1	Alembic Limited	03/24/2004		
	G W	GB	2395482	A	Jubilant Organosys Limited	05/26/2004		
	G X	JP	01038096	A	Pfizer Inc.	02/08/1989		+
	G Y	JP	01193292	A	Pfizer Inc.	08/03/1989		+
	G Z	JP	02083326	A	Pfizer Inc.	02/23/1990		+
	H A	JP	05132497	A	Pliva Pharmaceut & Chem Works	05/28/1993		+
	H B	JP	06184186	A	Pliva Pharmaceut & Chem Works	05/07/1994		+
	H C	JP	08041058	A	Pliva Pharmaceut	02/13/1996		+
	H D	JP	10072482	A	Astur Pharma SA	03/17/1998		+
	H E	JP	10316699	A	Hovione Inter Ltd.	12/02/1998		+
	H F	JP	41132276	A	Hovione Inter Ltd.	11/24/1999		+
	H G	JP	2000219697	A	Pfizer Prod. Inc.	08/08/2000		+

Examiner Signature	Date Considered
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FOREIGN PATENT DOCUMENTS								
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		Office	Application or Patent Number	Kind Code			Yes	No**
	HH	JP	2001187797	A	Astur Pharma SA	07/10/2000		+
	HI	WO	89/00576	A1	Pfizer Inc.	01/26/1989		
	HJ	WO	94/26758	A1	Pfizer Inc.	11/24/1994		
	HK	WO	95/30422	A1	Pfizer Inc.	11/16/1995		
	HL	WO	96/19489	A1	Russinsky Limited	06/21/1996		
	HM	WO	98/05674	A1	Russinsky Limited	02/12/1998		
	HN	WO	98/33482	A1	Abbott Laboratories	08/06/1998		
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OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	IH	PFIZER LABS, Division of Pfizer Inc., NY, NY 10017, "Zithromax," 70-5191-00-8 (October 2003)		

Examiner Signature		Date Considered	
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* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).